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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,812	02/04/2002	Richard J. Greff	034298-122	8436

7590 07/06/2005

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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/068,812

Applicant(s)

GREFF, RICHARD J.

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/26/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicants' request for RCE, amendment, and oath, all filed 04/26/2005; and change of power of attorney, filed 05/26/05.

Claims 1-17 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/26/2005 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by JP 02-182259 (259).

JP '259 disclosed composition comprising crosslinked gelatin, and solution comprising surfactant impregnated into the crosslinked gelatin (see the provided abstract).

4. Claims 1, 4, 5, 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 568334 ('334).

EP '334 disclosed hemostatic sponge comprising absorbable crosslinked gelatin and a solution of polyethylene glycol or glycerin in an amount of 10-30%, and collagen solution in an amount of 0.5 to 10%, and active agent such as growth factor, wherein the ingredients are soaked into the gelatin (abstract; col.2, lines 43-48; col.3, lines 43-52; col.4, lines 17-20, 43-47; col.5, lines 25-30; col.6, example 1; the claims). Any of collagen, polyethylene glycol, or glycerin reads on the claimed wetting agent. The collagen solution reads on the polymer listed in the wetting agent and glycerin reads on the surfactant. Decreasing the hydration time of the cross-linked gelatin that claimed in claim 5 is inherent in the material of the reference that comprises cross-linked gelatin and polyethylene glycol, and that has the polyethylene glycol incorporated with the cross-linked gelatin prior to use. The soaking of the gelatin into the solution of gelatin or polyethylene glycol will also form coating on the surface and that reads on coating the wetting agent on the surface of gelatin.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2, 3, 6, 7, 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '334.

The teachings of EP '334 are discussed under 102 rejection above. However, the reference does not teach impregnating the gelatin with the wetting agent before foaming, or the amount of the wetting agent in the gelatin composition after evaporation of the solvent.

Adding the wetting agent before or after foaming does not impart patentability to the claims because the claims are directed to composition and method of its use and the composition disclosed by the reference is capable of performing the same function as a hemostatic material.

It is expected to one having ordinary skill in the art to adjust the drying and evaporation of the solvent in order to obtain the desired concentration of the wetting agent in the composition, and the claimed concentration of the wetting agent in claim 14 does not impart patentability to the claims, absent evident to the contrary.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to obtain a composition comprising cross-linked gelatin

incorporating wetting agent as disclosed by EP '334 and select the method of production of the composition and adjust the degree of drying according to specific intended use and the desired form of the final product, with reasonable expectation of having a hemostatic composition that arrests bleeding at the site of application within a reasonable time.

7. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '334 in view of US 6,603,061 ('061).

The teachings of EP '334 are discussed under 102 rejection above. However, EP '334 does not teach the composition is sterile and packaged or the kit of syringe and pledget.

US '061 teaches a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin, plasticizer and hydrating agent (col.3, lines 4-6, 43, 67; col.4, lines 11-12, 41-42; col.5, line 40; col.8). The composition can be in the form of sterile packaged kit comprising the composition and a syringe and can be extruded from the syringe into intervertebral spaces, holes and pockets (col.3, lines 33-34; col.5, lines 6-10, 25-35; col.8, lines 32-36).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the hemostatic composition disclosed by EP '334 and deliver it by a syringe as disclosed by US '061, motivated by the teaching of US '061 that delivering the composition from a syringe allows the extrusion into intervertebral

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spaces, holes and pockets, with reasonable expectation of having hemostatic composition delivered from syringe into sites that are difficult to access.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,595,735 disclosed hemostatic composition comprising polyethylene glycol adsorbed on gelatin sponge; col.2, lines 35-66. US 4,920,158 disclosed hemostatic composition comprising crosslinked gelatin (GELFOAM) and glycerin, example 1.

Response to Arguments

9. Applicant's arguments with respect to claims 1-17 have been considered but are moot in view of the new ground(s) of rejection.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

Isis Ghali

ISIS GHALI
PATENT EXAMINER